UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BRAINTREE LABORATORIES, INC., Plaintiff, v. BRECKENRIDGE PHARMACEUTICAL, INC., Defendant.	)	Civil Action No. 12-cv-6851-AJN ECF Case

PLAINTIFF BRAINTREE LABORATORIES, INC.'S COUNTERSTATEMENT TO BRECKENRIDGE PHARMACEUTICAL, INC.'S RULE 56.1 STATEMENT OF MATERIAL FACTS IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT

Pursuant to the Federal Rules of Civil Procedure and Local Civil Rule 56.1, Plaintiff Braintree Laboratories, Inc. ("Braintree") submits this Counterstatement to Defendant Breckenridge Pharmaceutical, Inc.'s ("Breckenridge") Rule 56.1 Statement of Material Facts in support of its Motion for Summary Judgment of Noninfringement.

GENERAL OBJECTIONS

1. Braintree objects to Breckenridge's Statement because it mischaracterizes and/or inaccurately and incompletely describes certain of the cited documents and statements therein. *See* Fed. R. Civ. P. 56(c); Local Civil Rule 56.1.

2. Braintree objects to Breckenridge's Statement because it contains numerous facts that are not material and are irrelevant to its Motion for Summary Judgment of Noninfringement, which purportedly is based only on the claim term "from about 100 ml to about 500 ml." *See* Fed. R. Civ. P. 56(c); Local Civil Rule 56.1. *See also* Dkt. No. 41, ¶¶ 3, 6; Dkt. No. 85 at 15, 17.

3. Braintree objects to Breckenridge's Statement because it asserts alleged facts in an attempt to reargue the claim construction of "purgation" adopted by Judge Sheridan and affirmed by the Federal Circuit in the *Novel Case*, which Breckenridge has stipulated not to contest. Dkt. No. 41, ¶ 3; Brown Decl., Ex. 6, at 11; Ex. 13, at 5-8.[1]

4. Braintree objects to any characterization of the limitation "from about 100 ml to about 500 ml" that ignores the functional limitation "for inducing purgation" recited in each of the asserted claims of U.S. Patent 6,946,149 ("the '149 patent"). Dkt. No. 41, ¶¶ 3, 6.

[1] References in this document to the "Brown Decl." are to the Declaration of Jennifer Brown in Support of Braintree Laboratories, Inc.'s Opposition to Breckenridge Pharmaceutical, Inc.'s Motion for Summary Judgment of Noninfringement, filed concurrently herewith.

BRAINTREE'S RESPONSES TO BRECKENRIDGE'S STATEMENT

Without waiving the aforementioned General Objections, and incorporating each General Objection by reference into the responses below, Braintree responds to the individually numbered list of allegedly undisputed facts asserted in Breckenridge's Statement as follows:

THE PROPOSED LABELING FOR BRECKENRIDGE'S ANDA PRODUCT AND THE FDA-APPROVED LABEL FOR SUPREP®

1. Breckenridge Pharmaceutical, Inc. ("Breckenridge") is the owner of Abbreviated New Drug Application ("ANDA") No. 204135, for a generic version of Braintree's SUPREP® drug product (the "Breckenridge ANDA Product"). SF9.[2]

   RESPONSE: Undisputed.

2. The proposed labeling for Breckenridge's ANDA Product contains an "Indications and Usage" section, which states in full: "Sodium Sulfate, Potassium Sulfate, and Magnesium Sulfate Oral Solution Bowel Prep Kit is indicated for cleansing of the colon as a preparation for colonoscopy in adults." Ex. A, CYPRESS000038. *See also*, SF20.

   RESPONSE: Undisputed.

3. Braintree holds approved New Drug Application ("NDA") No. 22372 for SUPREP® Bowel Prep Kit ("SUPREP"). SF1.

   RESPONSE: Undisputed.

[2] References to "SF" in this document refer to the Stipulated Facts for Purposes of Breckenridge's Motion for Summary Judgment of Noninfringement, which is attached as Exhibit 11 to the Brown Declaration, filed concurrently herewith.

4. The proposed labeling for Breckenridge's ANDA Product is the same, in all relevant and material respects, as Braintree's FDA-approved label for SUPREP. SF28. *See also*, Ex. B; SF42; SF43.

RESPONSE: Undisputed.

5. Breckenridge's proposed generic version of SUPREP has the same composition, dosage form and route of administration as Braintree's SUPREP. SF13.

RESPONSE: Undisputed.

6. The sole FDA-approved indication for the SUPREP product is "cleansing of the colon as a preparation for colonoscopy in adults." Ex. B, CYPRESS000134. *See also*, SF4; SF42; SF43.

RESPONSE: Undisputed that the FDA-approved indication for SUPREP is "cleansing of the colon as a preparation for colonoscopy in adults."

7. Breckenridge's ANDA Product will be sold as a kit containing two six ounce bottles of concentrated sodium sulfate, potassium sulfate, and magnesium sulfate solution. Ex. A, CYPRESS000036, CYPRESS000039. *See also*, SF22.

RESPONSE: Undisputed that Breckenridge's ANDA product will be sold as a kit containing two six-ounce bottles, each bottle of which contains an identical composition of 17.5 grams of sodium sulfate, 3.13 grams of potassium sulfate, and 1.6 grams of magnesium sulfate.

8. According to the proposed label for Breckenridge's proposed generic version of SUPREP, each six ounce bottle of Breckenridge's generic version of SUPREP must be diluted with water to sixteen ounces prior to administration. SF23.

RESPONSE: Undisputed.

9. Sixteen ounces ("oz") is equal to approximately 473 milliliters ("ml"). SF27.

RESPONSE: Undisputed.

10. The proposed labeling for Breckenridge's ANDA product, in the Warnings and Precautions section of the Highlights of Prescribing Information, states: "Not for direct ingestion - dilute and take with additional water (5.8)." Ex. A, CYPRESS000037.

RESPONSE: Undisputed.

11. Paragraph 5.8 of the Warnings and Precautions section of the proposed labeling for Breckenridge's ANDA product states:

> 5.8 **Not for Direct Ingestion**
> Each bottle must be diluted with water to a final volume of 16 oz and ingestion of additional water as recommended is important to patient tolerance. Direct ingestion of the undiluted solution may increase the risk of nausea, vomiting, dehydration, and electrolyte disturbances.

Ex. A, CYPRESS000041.

RESPONSE: Undisputed.

12. The following is a true and accurate excerpt of the proposed labeling for Breckenridge's ANDA product, showing the "Dosage and Administration" section of the Full Prescribing Information:

> **2 DOSAGE AND ADMINISTRATION**
>
> Sodium sulfate, potassium sulfate, and magnesium sulfate oral solution bowel prep kit should be taken as a split-dose oral regimen.
>
> The dose for colon cleansing requires administration of two bottles of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution bowel prep kit. Each bottle is administered as 16 oz of diluted sodium sulfate, potassium sulfate, and magnesium sulfate oral solution bowel prep kit with an additional 1 quart of water taken orally. The total volume of liquid required for colon cleansing (using two bottles) is 3 quarts (approximately 2.8 L) taken orally prior to the colonoscopy in the following way:

Split-Dose (Two-Day) Regimen

Day prior to colonoscopy:

- A light breakfast may be consumed, or have only clear liquids on the day before colonoscopy. Avoid red and purple liquids, milk, and alcoholic beverages.
- Early in the evening prior to colonoscopy: pour the contents of one bottle of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution bowel prep kit into the mixing container provided. Fill the container with water to the 16 oz fill line, and drink the entire amount.
- Drink two additional containers filled to the 16 oz line with water over the next hour.

Day of colonoscopy:

- Have only clear liquids until after the colonoscopy. Avoid red and purple liquids, milk, and alcoholic beverages.
- The morning of colonoscopy (10 to 12 hours after the evening dose): pour the contents of the second bottle of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution bowel prep kit into the mixing container provided. Fill the container with water to the 16 oz fill line, and drink the entire amount.
- Drink two additional containers filled to the 16 oz line with water over the next hour.
- Complete all sodium sulfate, potassium sulfate, and magnesium sulfate oral solution bowel prep kit and required water at least one hour prior to colonoscopy.

Ex. A, CYPRESS000038-39. *See also*, SF23; SF33; SF34; SF40.

RESPONSE: Undisputed.

13. The proposed label for Breckenridge's proposed generic version of SUPREP contained in ANDA No. 204135 instructs healthcare professionals how to prescribe and patients how to use Breckenridge's proposed generic version of SUPREP. SF30.

RESPONSE: Undisputed.

14. The Breckenridge ANDA Product, administered according to its proposed label, requires the patient to consume two 16 ounce containers (*i.e.*, 946 ml) of sodium

sulfate, potassium sulfate, and magnesium sulfate aqueous solution. Ex. A, CYPRESS000038-39. *See also*, SF33, SF34; SF36.

RESPONSE: **Disputed** because DF[3] 14 is an incomplete description of the administration of the Breckenridge ANDA Product. Breckenridge's proposed generic copy of SUPREP, administered according to its proposed label, instructs the patient to consume two 6-ounce bottles of sodium sulfate, potassium sulfate, and magnesium sulfate aqueous solution diluted with water to 16 ounces, administered according to a split-dose (two day) regimen. Dkt. No. 86-1 at CYPRESS000007-8. The 16-ounce containers of diluted solution are consumed in two separate administrations separated by 10-12 hours. *Id*. The proposed label for Breckenridge's generic copy of SUPREP does not instruct the patient to consume 946 ml of sodium sulfate, potassium sulfate, and magnesium sulfate aqueous solution in a single, continuous administration.

15. The SUPREP product, administered according to its FDA-approved label, also directs the patient to consume two 16 ounce containers (about 473 ml each for a total of about 946 ml) of sodium sulfate, potassium sulfate, and magnesium sulfate aqueous solution in two administrations during the treatment period. SF35.

RESPONSE: **Disputed** because DF 15 is an incomplete description of the administration of SUPREP. SUPREP, administered according to its FDA-approved label, instructs the patient to consume two 6-ounce bottles of sodium sulfate, potassium sulfate, and magnesium sulfate aqueous solution diluted with

[3] References in this document to "DF" are to the material facts submitted by Defendant Breckenridge in support of its Motion for Summary Judgment of Noninfringement.

water to 16 ounces, administered according to a split-dose (two day) regimen. Brown Decl. Ex. 10 at BRTSUP00000129-130. The 16-ounce containers of diluted solution are consumed in two separate administrations separated by 10-12 hours. *Id*. The SUPREP label does not instruct the patient to consume 946 ml of sodium sulfate, potassium sulfate, and magnesium sulfate aqueous solution in a single, continuous administration.

16. The proposed labeling for Breckenridge's ANDA Product states "The dose for colon cleansing requires administration of two bottles of sodium sulfate, potassium sulfate, and magnesium sulfate oral solution bowel prep kit." SF33. *See also*, SF34.

RESPONSE: **Disputed** because DF 16 is an incomplete description of the administration of the Breckenridge ANDA Product. Breckenridge's proposed generic copy of SUPREP, administered according to its proposed label, instructs the patient to consume two 6-ounce bottles of sodium sulfate, potassium sulfate, and magnesium sulfate aqueous solution diluted with water to 16 ounces, administered according to a split-dose (two day) regimen. Dkt. No. 86-1 at CYPRESS000007-8. The 16-ounce containers of diluted solution are consumed in two separate administrations separated by 10-12 hours. *Id*. The proposed label for Breckenridge's proposed generic copy of SUPREP does not instruct the patient to consume 946 ml of sodium sulfate, potassium sulfate, and magnesium sulfate aqueous solution in a single, continuous administration.

17. Breckenridge's proposed labeling does not include any indication for the Breckenridge ANDA Product that would involve administration of only a single bottle of the Breckenridge ANDA Product. Ex. A. *See also*, SF20; SF33; SF34.

RESPONSE: **Undisputed** that Breckenridge's proposed labeling does not include any indication for the Breckenridge ANDA Product that would involve administration of a total of only a single bottle of the Breckenridge ANDA Product over the entire course of treatment. **Disputed** to the extent DF 17 alleges that two bottles of the Breckenridge ANDA Product could, in accordance with the label, be administered without administering a single bottle of Breckenridge's ANDA Product 10-12 hours before administration of the second bottle.

THE '149 PATENT

18. The Abstract of the '149 Patent states:

> The field of colonic diagnostic and surgical procedures is hampered by the lack of optimal means available to cleanse the colon. A compromise between convenient, distasteful, solid or low volume, hyperosmotic solutions which cause considerable fluid and electrolyte imbalances in patients and large volume, difficult to consume, iso-osmotic solutions has had to be made heretofore.

Ex. D, Abstract.

RESPONSE: **Undisputed**. **Irrelevant to the Court's decision**. This alleged fact is irrelevant to Breckenridge's sole noninfringement argument because, among other reasons, it relates to claim construction. Dkt. No. 41, ¶¶ 3, 6; Dkt. No. 85 at 15, 17.

19. The '149 Patent states:

> There are two currently used methods used for colonic lavage. These are: (1) gastrointestinal lavage with 4 liters of a balanced solution that causes negligible net water or electrolyte absorption or secretion or (2) oral ingestion of small volumes of concentrated

> (hypertonic) sulfate or sodium phosphate solutions, e.g. Fleet Phospho-Soda, or the non-aqueous tablet formulations of phosphates or salts, all of which cause clinically significant effects on bodily chemistry.
>
> Clinical trials have shown use of the 4 liter balanced solution to be safe and efficacious. However, compliance is poor because of the large volume of solution that must be rapidly ingested. Additionally, these large volume solutions are not well tolerated by patients.

Ex. D, 3:59-4:5.

RESPONSE: **Undisputed**. **Irrelevant to the Court's decision**. This alleged fact is irrelevant to Breckenridge's sole noninfringement argument because, among other reasons, it relates to claim construction. Dkt. No. 41, ¶¶ 3, 6; Dkt. No. 85 at 15, 17.

20. The "Background Information" section of the '149 Patent discusses the "brand name Fleets Phospho-Soda™" formulation, stating:

> Patients are typically required to take two (2) three ounce doses of this preparation, separated by a three to 12 hour interval for a total of six ounces (180 ml), which is a significant reduction compared to the large 1 gallon volumes required by the high volume preparations . . . .
>
> These small volume sulfate/phosphate solutions and non-aqueous formulations have been shown to cause massive electrolyte and fluid shifts that are clinically significant to the patient . . . .

Ex. D, 2:31-36, 2:41-43.

RESPONSE: **Undisputed**. **Irrelevant to the Court's decision**. This alleged fact is irrelevant to Breckenridge's sole noninfringement argument because, among other reasons, it relates to claim construction. Dkt. No. 41, ¶¶ 3, 6; Dkt. No. 85 at 15, 17.

21. The "Examples" section of the '149 Patent states that "Fleet Phospho-Soda . . . 90 mL, was added to 240 mL of water, for a volume of 330 mL. One half of this diluted solution was ingested by the subjects on two occasions, at 7 p.m. on day 1 and again at 5 a.m. on day 2." Ex. D, 5:56-61.

RESPONSE: Undisputed. Irrelevant to the Court's decision. This alleged fact is irrelevant to Breckenridge's sole noninfringement argument because, among other reasons, it relates to claim construction. Dkt. No. 41, ¶¶ 3, 6; Dkt. No. 85 at 15, 17.

22. The '149 Patent states: "The ingested experimental solutions were also 330 mL in volume . . . One half of each experimental solution was ingested by the subjects on two occasions, at 7 p.m. on day 1 and at 5 a.m. on day 2." Ex. D, 5:64-6:3.

RESPONSE: Undisputed. Irrelevant to the Court's decision. This alleged fact is irrelevant to Breckenridge's sole noninfringement argument because, among other reasons, it relates to claim construction. Dkt. No. 41, ¶¶ 3, 6; Dkt. No. 85 at 15, 17.

23. During prosecution of the '149 patent, the inventors distinguished their invention from several prior art disclosures of larger volume colon cleansing preparations. Ex. E, 9-11; Ex. F, 9-10; Ex. H, 1; Ex. J, 4.

RESPONSE: Disputed because DF 23 is vague, ambiguous and incomplete. **Irrelevant to the Court's decision.** In addition, this alleged fact is irrelevant to Breckenridge's motion because, among other reasons, it relates to claim construction. Dkt. No. 41, ¶¶ 3, 6; Dkt. No. 85 at 15, 17.

24. During prosecution of the '149 Patent, Braintree distinguished U.S. Patent No. 6,235,745 ("Megens"), stating in part:

> Furthermore, Megens' broadest teaching when combined with Davis does not teach the Applicants' claimed composition for inducing purgation of the colon comprising a small volume of an aqueous hypertonic solution (*e.g.*, about 100 ml to about 500 ml) comprising one or more salts selected from the group consisting of Na_2S0_4, $MgS0_4$, and K_2S0_4, with or without an effective amount of PEG, or a method for inducing colonic purgation comprising the steps of providing the aforementioned composition. Megens' test subjects were small dogs weighing no more than about 30 pounds. If extrapolated to average adult human weight, (e.g., about 150 lbs.) that volume would be about 1 liter to about 1.5 liters, not a small volume (e.g., about 100 ml to about 500 ml) claimed in the instant invention.

Ex. E, p. 11 (emphasis in original).

RESPONSE: **Undisputed** that this excerpt appears in the file history of the '149 patent. **Irrelevant to the Court's decision.** In addition, this alleged fact is irrelevant to Breckenridge's motion because, among other reasons, it relates to claim construction. Dkt. No. 41, ¶¶ 3, 6; Dkt. No. 85 at 15, 17.

25. The '149 Patent originally issued with claims to "small volume" compositions. *See, e.g.*, Ex. D, 11:65-12:5, 12:23-30, 12:63-13:2, 13:10-16.

RESPONSE: **Undisputed**. **Irrelevant to the Court's decision.** In addition, this alleged fact is irrelevant to Breckenridge's motion because, among other reasons, it relates to claim construction. Dkt. No. 41, ¶¶ 3, 6; Dkt. No. 85 at 15, 17.

26. Braintree requested *ex parte* reexamination of the '149 Patent, and submitted proposed claims that replaced the term "small volume" in all claims with "about 100 ml to about 500 ml." Ex. F; Ex. G.

RESPONSE: Undisputed.

27. Braintree distinguished each of the prior art references Russell, Nissho, and Guiliani in part by stating that those references do not disclose the use of "about 100 ml to about 500 ml." Ex. F, at 9-10; Ex. J, at 4.

RESPONSE: Disputed because DF 27 is vague, ambiguous, incomplete and cites portions of the prosecution history out of context. **Irrelevant to the Court's decision**. In addition, this alleged fact is irrelevant to Breckenridge's motion because, among other reasons, it relates to claim construction. Dkt. No. 41, ¶¶ 3, 6; Dkt. No. 85 at 15, 17.

28. Braintree argued the patentability of the claimed compositions over Nissho by, among other things, stating: "Nor does Nissho disclose the use of about 100 ml to about 500 ml, rather Nissho discloses the use of 2 liters. Nissho fails to disclose or even suggest the use of the claimed combination of salts at a significantly lower volume." Ex. F, 10; *see also* Ex. H, 1.

RESPONSE: Disputed because DF 28 is vague, ambiguous, incomplete and cites portions of the prosecution history out of context. **Irrelevant to the Court's decision**. In addition, this alleged fact is irrelevant to Breckenridge's motion because, among other reasons, it relates to claim construction. Dkt. No. 41, ¶¶ 3, 6; Dkt. No. 85 at 15, 17.

29. Nissho states that dilution of a powder composition with "additional water … to make a total volume of two liters" resulted in preparation of "an emulsified liquid agent (i.e., lavage solution according to the present invention) for one administration." Ex. L, 4:3-10.

RESPONSE: **Disputed** because DF 29 is vague, ambiguous, incomplete and cites portions of the reference out of context. **Irrelevant to the Court's decision**. In addition, this alleged fact is irrelevant to Breckenridge's motion because, among other reasons, it relates to claim construction. Dkt. No. 41, ¶¶ 3, 6; Dkt. No. 85 at 15, 17.

30. Braintree argued the patentability of the claimed compositions over Giuliani by, among other things, stating: "While Giuliani discloses Na_2S0_4, Giuliani does not disclose a composition containing Na_2S0_4, $MgS0_4$, and K_2S0_4 (p. 3, 1. 23). With regard to the volume, Giuliani discloses 4 L (p. 3, 1. 20), not about 100 ml to about 500 ml." Ex. J, 4.

RESPONSE: **Disputed** because DF 30 is vague, ambiguous, incomplete and cites portions of the prosecution history out of context. **Irrelevant to the Court's decision**. In addition, this alleged fact is irrelevant to Breckenridge's motion because, among other reasons, it relates to claim construction. Dkt. No. 41, ¶¶ 3, 6; Dkt. No. 85 at 15, 17.

31. Guiliani discloses a "Formula for one dose to make 0.5 litres of extemporaneous solution," and lists "Gastrointestinal wash maximum dose 4 l." Ex. K, 3:15-20.

RESPONSE: **Disputed** because DF 31 is vague, ambiguous, incomplete and cites portions of the reference out of context. **Irrelevant to the Court's decision**. In addition, this alleged fact is irrelevant to Breckenridge's motion because, among other reasons, it relates to claim construction. Dkt. No. 41, ¶¶ 3, 6; Dkt. No. 85 at 15, 17.

32. The United States Patent and Trademark Office issued a Reexamination Certificate of the '149 Patent on June 30, 2009. Ex. C.

RESPONSE: **Undisputed.**

33. Following reexamination, the only independent claims of the '149 Patent are claims 2, 7, 15, and 18. Ex. C.

RESPONSE: **Undisputed.**

34. Following reexamination, every claim of the '149 Patent requires a composition "comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution." Ex. C; Ex. D, 11:65-14:20.

RESPONSE: **Undisputed.**

35. Claim 15, as amended through reexamination, is representative of the composition claims at issue in this case, and reads:

> 15. A composition for inducing purgation of the colon of a patient, the composition comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution comprising an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4, wherein the composition does not produce any clinically significant electrolyte shifts and does not include phosphate.

Ex. C, 2:23-31.

RESPONSE: Disputed. Reexamined claims 15 and 18 are distinct claims in the '149 patent. Undisputed that claim 15 of the '149 patent is reproduced in DF 35.

36. Claim 20 is representative of the method claims at issue in this case, and reads:

> A method for including colonic purgation in a patient, comprising the steps of:
>
> (a) orally administering an effective amount of the composition of claim 15 to a patient; and

> (b) allowing the administered composition to induce colonic purgation.

Ex. D, 14:3-8. *See also*, Ex. C., 2:23-31 (independent claim 15, as amended through reexamination).

RESPONSE: **Disputed**. Each of the method claims of the '149 patent is a distinct claim. Undisputed that claim 20 of the '149 patent is reproduced in DF 36.

37. Claim 23 depends from claim 20 and reads:

> A method for inducing colonic purgation in a patient according to claim 20, wherein the effective amount of the composition is administered in two or more doses within a treatment period.

Ex. D, 14:15-19.

RESPONSE: **Undisputed.**

38. Braintree filed a Request for Extension of Patent Term on September 30, 2010. Ex. M, 1.

RESPONSE: **Undisputed**. **Irrelevant to the Court's decision.** In addition, this alleged fact is irrelevant to Breckenridge's motion because, among other reasons, it relates to claim construction. Dkt. No. 41, ¶¶ 3, 6; Dkt. No. 85 at 15, 17.

39. In its Request for Extension of Patent Term, Braintree stated:

> The SUPREP product comprises a small volume. Specifically, the product contains only 2 x 16 ounces of solution (*i.e.*, approximately 2 x 0.47 L = .94 L of solution), as indicated in the approved label (Exhibit 3). The '149 specification defines "small volume" as less than one liter of water, *e.g.*, 100-500 ml of water (see column 5, lines 15-20). Moreover, claim 17, which depends from claim 15, requires that the "solution is from about 100 ml to about 500 ml in volume." Based on the doctrine of claim differentiation, it is evident that "small volume" includes a volume

> of at least 100 ml to 500 ml, e.g., a volume higher than 500 ml, such as the 0.94L solution in the SUPREP product.

Ex. M, at 11.

RESPONSE: **Undisputed** that the cited excerpt appears in the Request for Extension of Patent Term filed September 30, 2010. **Irrelevant to the Court's decision.** In addition, this alleged fact is irrelevant to Breckenridge's motion because, among other reasons, it relates to claim construction. Dkt. No. 41, ¶¶ 3, 6; Dkt. No. 85 at 15, 17.

Dated: July 20, 2015

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CERTIFICATE OF SERVICE

I hereby certify that on July 20, 2015, a true and correct copy of the foregoing PLAINTIFF BRAINTREE LABORATORIES, INC.'S COUNTERSTATEMENT TO BRECKENRIDGE PHARMACEUTICAL, INC.'S RULE 56.1 STATEMENT OF MATERIAL FACTS IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT was filed through the Court's Electronic Filing System (ECF), and was served electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

Dated: July 20, 2015 /s/ John J. Regan